

REMARKS

I. Introduction

Applicants acknowledge receipt of the Non-Final Office mailed August 9, 2004. Claims 36, 38, 41-55, and 95 are pending in the application. Claims 1-35, 37, 39-41, 50, and 52-95 have been canceled. Claims 36, 38, 47, 49, and 51 have been amended. Claim 96 has been added. Support for amended claim 36 may be found at page 10, Example 1B, of the specification. Support for amended claim 38 may be found at page 3, first paragraph of the specification. Support for amended claim 49 may be found at page 3, paragraph 3 of the specification. Support for amended claim 51 may be found at page 3, paragraph 4 of the specification. Support for new claim 96 may be found at page 10, second paragraph of the specification. No new matter has been added in the amendments.

II. Rejections Under 35 U.S.C. § 112, second paragraph

The Examiner has rejected claim 38 under 35 U.S.C. § 112 as being indefinite because allegedly the term "low" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, one of ordinary skill in the art would not reasonably be apprised of the scope of the invention, and the metes and bounds of the claim are not clear. In response, and without acquiescing in the rejection, Applicants have amended claim 38 to recite "wherein the concentration of said assimilable phosphorus is allowed to decrease to 0.00 % w/v after a fermentation time of 40 hours."

III. Claim Rejections Under 35 U.S.C. § 102(b)

The Examiner has maintained the rejection of claims 36, 38, 42-45, 47, 49, and 51-52 under 35 U.S.C. § 102(b) as being anticipated by Cole *et al.* (U.S. Patent No. 4,110,165) in view

of Stanbury *et al.* for essentially the same reasons cited in the Final Office Action of January 23, 2003 and the Non-Final Office Action of February 20, 2004. The Examiner has alleged that the processes of Examples 9 and 13 in Cole *et al.* meet the limitations of the claimed invention requiring that a microorganism be grown within the claimed phosphorus concentration range and requiring a decrease in the phosphorus concentration. Specifically, the Examiner has alleged that Cole *et al.* disclose processes for making clavulanic acid involving the cultivation of *Streptomyces clavuligerus* in a fermentation medium, wherein the potassium dihydrogen phosphate concentration is 0.1%, about 55% of the dipotassium hydrogen phosphate in the fermentation medium is assimilable phosphorus (i.e., 1.10 grams per liter of medium, or about 0.11%), no phosphorus is added during the fermentation, the fermentations last for 3-5 days, and soy flour is used as the nitrogen source. Cole *et al.* also allegedly disclose assimilable sources of carbon, nitrogen, and mineral salt, a maximum yield of clavulanic acid obtained within 2-10 days, with peak yields of clavulanic acid obtained within 5 days and optimum titres of clavulanic acid achieved between 3-5 days, a nutrient medium containing soya bean flour, and a KH_2PO_4 concentration of 0.1% in Example 13.

Applicants respectfully traverse this rejection. In order to reject a claim under 35 USC § 102, the Examiner must demonstrate that each and every claim element is contained in a single prior art reference. See *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 18 USPQ2d 1001, 1010 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 90 (Fed. Cir. 1986); see also MPEP § 2131 (August 2001). Claim terms are to be given their plain meaning as understood by the person of ordinary skill in the art, particularly given the limitations of the English language. See MPEP §§ 707.07(g); 2111.01 (August 2001). Not only must the claim terms, as reasonably interpreted, be present, an allegedly anticipatory reference must

enable the person of ordinary skill to practice the invention as claimed. Otherwise, the invention cannot be said to have been already within the public's possession, which is required for anticipation. *See Akzo, N.V. v. U.S.I.T.C.*, 1 USPQ2d 1241, 1245 (Fed. Cir. 1986); *In re Brown*, 141 USPQ 245, 249 (CCPA 1964). If the Examiner relies on more than one reference to prove the inherency of a missing element in a reference cited as § 102 prior art, such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991). *See also* MPEP § 2131.01. In relying upon the theory of inherency, the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that an allegedly inherent characteristic necessarily flows from the teachings of the prior art. *Ex parte Levy*, 17 USPQ2d 1461 (BPAI 1990). That one skilled in the art might interpret a prior art reference as teaching a feature of the claimed invention required for anticipation is not sufficient. *Finnigan Corp. v. Int. Trade Com'n.*, 180 F.3d 1354, 51 USPQ2d 1001 (CAFC 1999).

Applicants first note that the rejection of claim 52 is moot, in light of Applicants' cancellation of claim 52. Applicants further submit that *Cole et al.* in view of *Stanbury et al.* do not anticipate claims 36, 38, 42-45, 47, 49, or 51, as amended, because they do not teach or suggest every element of the amended claims. The claims, as amended, are distinct from *Cole et al.* in view of *Stanbury et al.* because the references teach that the concentration of the phosphorus source is maintained during the growth phase of the fermentation *after* the phosphorus present in the starting medium is consumed. While *Cole et al.* teaches that "Na⁺ or K⁻ salts of phosphoric acid *may* be added to the media" (emphasis added) (col. 10, lines 55-57), *Cole et al.* in view of *Stanbury et al.* do not teach or suggest that the phosphorus

concentration is maintained below 0.15% w/v during the growth phase of the fermentation *after* the phosphorus present in the starting medium is consumed or that the phosphorus in the starting medium is allowed to decrease after cessation of the growth phase.

The Examiner has newly alleged that the growth and stationary phases recited in amended claim 36 in Applicants' amendment filed May 19, 2004, are inherent in any batch fermentation process, including the batch fermentation process disclosed by Cole *et al.*, and that because the amended claims encompass batch processes wherein the phosphorus concentration is allowed to decrease with time, as allegedly occurs in Cole *et al.*, Cole *et al.*'s process anticipates the newly-added requirement regarding the phosphorus concentration during the growth phase. Without acquiescing in the rejection, Applicants have amended claim 36 to delete the phrase "wherein said fermentation comprises a growth phase and a stationary phase."

The Examiner has also newly alleged that contrary to the Applicants' arguments, Applicants have not provided evidentiary support for the assertion that the phosphorus concentrations in the examples of Cole *et al.* are not necessarily present at the beginning of the fermentations. Rather, the Examiner has alleged that the claimed phosphorus concentrations *are* present at the start of Cole *et al.*'s fermentations, and the claimed phosphorus concentrations are allowed to decrease because no phosphorus is added. Applicants respectfully traverse this rejection. Applicants point out that although several of the examples of Cole *et al.* may teach the use of phosphorus in the starting cultivation medium, Applicants submit that even if the allegedly inherent characteristic of phosphorus decreasing in the medium after the growth phase of the fermentation necessarily flows from the teaching of Cole *et al.*, this alleged feature of Cole *et al.* is irrelevant in light of the amended claims which distinguish the claimed invention from the prior art by the maintenance of the phosphorus concentration during the growth phase of

fermentation after the initial phosphorus present in the media is consumed. Therefore, Applicants respectfully request that the Examiner withdraw this rejection.

IV. Claim Rejections Under 35 U.S.C. § 103(a)

The Examiner has maintained the rejection of claims 36, 38, 41-47, and 49-54, and has rejected new claim 95 under 35 U.S.C. § 103(a) as being unpatentable over Cole *et al.* (U.S. Patent No. 4,110,165). The Examiner has maintained the rejection of claims 36, 38, 41-47, and 49-54 for essentially the same reasons cited in the Final Office Action mailed January 23, 2003 and the Non-Final Office Action of February 20, 2004.

A. Cole *et al.*

The Examiner has alleged that Cole *et al.* allegedly anticipate claims 36, 38, 42-45, 47, 49, 51, and 52 for the reasons mentioned above. The Examiner has further alleged that Cole *et al.* do not disclose a phosphorus concentration of about 0.008%, as recited in claim 41, or the range of carbon source concentrations recited in amended claim 50, but that the phosphate concentrations would be *prima facie* obvious because Cole *et al.* allegedly disclose the desirability of phosphate in the fermentation media, and one of ordinary skill in the art could determine suitable phosphate concentrations through routine experimentation, absent unexpected results.

The Examiner has maintained the rejection of claim 46 and has stated that the use of sodium dihydrogen phosphate as the phosphorus source, recited in claim 46, must be considered obvious over Cole *et al.*'s disclosed use of potassium dihydrogen phosphate as the phosphorus source. The Examiner has alleged that one of ordinary skill in the art would reasonably expect the salts of potassium and sodium to function substantially equivalently in the processes

disclosed by Cole *et al.* in view of Cole *et al.*'s disclosure that either of the salts of the phosphoric acid may be used. The Examiner has alleged that both sodium and potassium phosphate salts are well known in the fermentation arts and are equivalent to the extent that they are both suitable in the preparation of aqueous solutions.

Applicants respectfully traverse these rejections. Applicants again remind the Examiner that M.P.E.P. § 2142 sets forth three requirements that must be met in order to establish a *prima facie* case of obviousness under § 103. First, there must be some suggestion or motivation, either in the references themselves, or in the knowledge generally available to one of ordinary skill in the art, to modify or combine the references. Second, there must be a reasonable expectation of success upon combining such references. Finally, the prior art references, when combined, must teach or suggest all of the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on the Applicants' disclosure. *In re Vaeck*, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991); *In re Dow Chemical Co.*, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988); *W.L. Gore v. Garlock, Inc.*, 220 USPQ 303, 312-13 (Fed. Cir. 1983) (it is improper in combining references to hold against the inventor what is taught in the inventor's application); *see also* M.P.E.P. §§ 2142-43 (February 2003). Thus, the Examiner must provide evidentiary support based upon the contents of the prior art to support all facets of the rejection, rather than just setting forth conclusory statements, subjective beliefs, or unknown authority. *See In re Lee*, 277 F.3d 1338, 1343-44 (Fed. Cir. 2002). When an Examiner alleges a *prima facie* case of obviousness, such an allegation can be overcome by showing that (i) there are elements not contained in the references or within the general skill in the art, (ii) the combination is improper (for example, there is a teaching away or no reasonable expectation of success) and/or (iii) objective indicia of patentability exist (for

example, unexpected results). See *U.S. v. Adams*, 383 U.S. 39, 51-52 (1966); *Gillette Co. v. S.C. Johnson & Son, Inc.*, 16 USPQ2d 1923, 1927 (Fed. Cir. 1990); *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve*, 230 USPQ 416, 419-20 (Fed. Cir. 1986). Applicants submit that the rejections do not meet this test.

Applicants first note that the rejections of claims 41, 50, 52-54, and 95 are moot in light of Applicants' cancellation without prejudice of these claims. In response to rejected claims 36, 38, 42-45, 47, 49, and 51, Applicants reiterate the distinguishing arguments set forth above. Applicants further maintain that one of ordinary skill in the art would not have been motivated to substitute the assimilable phosphorus source of NaH_2PO_4 in claim 46 of the claimed invention for the KH_2PO_4 assimilable phosphorus source taught in *Cole et al.* because, as stated in Applicants' previous response, NaH_2PO_4 and KH_2PO_4 have different properties (see Declaration, tab A of the Appendix). NaH_2PO_4 is freely soluble in water and loses its water at 100° . In contrast, KH_2PO_4 is much less soluble in water and loses its water at 400° . Therefore, the properties of NaH_2PO_4 and KH_2PO_4 affect the clavulanic acid yield differently. In the present invention, 3,580 $\mu\text{g/ml}$ of clavulanic acid was obtained as a result of using NaH_2PO_4 as opposed to a much lower yield of 200-500 $\mu\text{g/ml}$ of clavulanic acid when KH_2PO_4 was used in *Cole et al.* (Examples 12 and 13). Thus, one of ordinary skill in the art would more likely use NaH_2PO_4 to maximize the yield of clavulanic acid.

The Examiner has further alleged that because the claims under examination are essentially identical or substantially similar to the processes disclosed by *Cole et al.*, the alleged unexpected results must be due to some unclaimed aspect of the process disclosed by the Applicant. The Examiner has alleged that the processes in Applicants' specification contain many parameters and specific strains, none of which are recited in the claims under examination.

The Examiner has further alleged that no step of adding phosphorus during the fermentation process is recited in the claims and that the unexpected results are not commensurate in scope with the claims under examination (*see* page 3, paragraph 2 of the Office Action).

In response, Applicants submit that the unexpected result of the present invention, compared to the prior art, is the significantly improved clavulanic acid yield. This is a direct result of the maintenance of the phosphorus source (phosphate) concentration in the range of between 0.0015% w/v and 0.15% w/v during the growth phase after the first hours of fermentation, wherein the starting phosphorus source is consumed after a fermentation time of 40 hours.

The maintenance of the phosphate source in the present invention is supported in the specification at page 10, last line to page 11, which teaches that the concentration of assimilable sources of phosphorus in the fermentation broth were used during the growth phase of the fermentation. The specification also teaches at page 11, last paragraph, that "The pH value reached *in the first hours of the culture growth* rose to almost 7.5. *During this time phosphorus was consumed*, and clavulanic acid started to be produced ..." (emphasis added). Thus, in the first hours of fermentation the assimilable source of phosphorus is consumed, and no new assimilable source of phosphorus is used after 40 hours (page 3 of the specification, lines 4-5).

The phosphorus source used in the instant invention that is maintained between 0.0015% w/v and 0.15% w/v also regulates the synthesis of clavulanic acid and/or its salts. The inhibitory effect of phosphate on the synthesis of clavulanic acid by *Streptomyces clavuligerus* is described in Romero J. *et al.*, *Applied Microbiology and Biotechnology*, 20:318 (1984) (*see* Declaration, tab B of Appendix). Romero *et al.* teach that "addition of ...phosphate ... resulted in a concentration-dependent reduction of clavulanic acid biosynthesis" (p. 321, left col.). This

result is confirmed by Lebrihi A. *et al.*, *Applied Microbiology and Biotechnology*, 26:130 (1987) (see Declaration, tab C of Appendix). Lebrihi *et al.* teach that as phosphate is added to the fermentation medium, the production of clavulanic acid decreases because phosphate controls the biosynthesis of clavulanic acid by a repression of the clavulanic acid synthetase enzymatic system. Therefore, the results of the present invention are completely unexpected and unobvious in view of Cole *et al.* because Cole *et al.* do not teach that after the first hours of fermentation when the phosphorus source (phosphate) present at the beginning of the fermentation is consumed, followed by the maintenance of the phosphorus source (phosphate) is below a limit of 0.15% w/v during the growth phase of fermentation, *after* which the phosphorus concentration is allowed to decrease. Neither do Cole *et al.* show any relationship between the phosphate present in the starting fermentation medium or the maintenance of the phosphate concentration during the growth phase of fermentation.

As further evidence of the instant invention's completely unexpected effects, Applicants point to Example 1B on pages 9-10 of the specification, wherein clavulanic acid is obtained from *Streptomyces sp 6621 FERM P2804* in an amount of 3,580 mg/l (3,580 µg/ml) (see page 3, paragraph 2 of the specification) of clavulanic acid, which is significantly and unexpectedly higher than the prior art processes cited by the Examiner (i.e., 200-500 µg/ml cited in Examples 12 and 13).

Applicants note that the unexpected results of the present invention do not merely arise from the substitution of one *Streptomyces clavuligerus* species for another. For instance, Example 1(a) of the present invention uses the culture *Streptomyces sp. PP 6621 FERM P2804*. Applicants submit herewith a declaration that includes an additional fermentation example of clavulanic acid using the microorganism *Streptomyces clavuligerus ATTC 27064* (see

Declaration, tab D of the Appendix) which also gives an unexpectedly high yield of clavulanic acid (4410 $\mu\text{g/ml}$) (*see* page 1, paragraph 3 and page 4, lines 10-11 of the specification, arguing that the invention gives improved yields of clavulanic acid from *S. clavuligerus*). Applicants further note that the additional strain *S. clavuligerus* ATTC 27064 enclosed in the declaration is identical to the strain *S. clavuligerus* NRRL 3585 cited in the specification (*see* specification at page 1, paragraph 3 and page 4, second paragraph; Declaration, tab E of the Appendix).

Thus, Applicants respectfully submit that the unexpected results of the present invention do not arise from the starting phosphorus concentration or a particular species of *Streptomyces clavuligeris*. Rather, the unexpected effects of the present invention arise from the maintenance of the phosphorus source during the growth phase of the fermentation, and whether the starting phosphorus concentration in the broth of Cole *et al.* falls within the value of the present invention is irrelevant.

B. Cole *et al.* in view of Stanbury *et al.*

The Examiner has rejected claims 36, 38, 41-55, and 95 under 35 U.S.C. § 103(a) as being unpatentable over Cole *et al.* (U.S. Patent No. 4,110,165) in view of Stanbury *et al.* The Examiner has maintained the rejection of claims 36, 38, 41-55, and 95 for essentially the same reasons cited in the Final Office Action mailed January 23, 2003 and the Non-Final Office Action of February 20, 2004. The Examiner has asserted that while Cole *et al.* allegedly anticipate claims 36, 38, 42-45, 47, 49, 51, and 52 for the reasons mentioned above, Cole *et al.* do not disclose conducting fed-batch or continuous process fermentations as recited in claims 48 and 55. The Examiner has alleged that one of ordinary skill in the art would have been motivated to use a 0.1% phosphorus concentration in a fed-batch or continuous process production of clavulanic acid because Cole *et al.* disclose that this concentration is desirable in

fed-batch fermentations which produce antibiotics such as penicillin disclosed by Stanbury *et al.*, and clavulanic acid is similar to penicillin.

In response, Applicants note that the rejection of claims 41, 50, 52-55, and 95 has been rendered moot in view of Applicants' cancellation without prejudice of these claims. Applicants reiterate the distinguishing arguments set forth above in response to the Examiner's rejection of claims 36, 38, and 42-51. Regarding claim 48, the Examiner has further maintained the rejection that although Cole *et al.* do not exemplify a combination of a continuous process with the claimed phosphorus concentrations, one of ordinary skill in the art would allegedly find it useful to use a continuous fermentation process using the claimed phosphorus concentrations because Cole *et al.* state that the fermentation may be carried out in a continuous manner. The Examiner has alleged that with respect to the impracticability of Cole *et al.*'s disclosure of the advantages of fed-batch processes in penicillin as disclosed by Stanbury *et al.*, Stanbury *et al.* clearly suggest that those advantages may be generally applicable to antibiotic production. Furthermore, the Examiner has alleged that Cole *et al.* teach that clavulanic acid is antibacterial.

Applicants respectfully traverse this rejection. Claim 48 refers to the assimilable phosphorus source in amended claim 36 that is used to maintain the phosphorus concentration during the growth phase of the fermentation after the phosphorus is consumed, which is not a feature taught in Cole *et al.* Therefore, any motivation to combine the allegedly continuous fermentation taught by Stanbury *et al.* with the clavulanic acid of Cole *et al.* because clavulanic acid is allegedly functionally identical and similar to penicillin would be irrelevant. Therefore, it would not be obvious to combine Cole *et al.* with Stanbury *et al.* to produce the claimed invention, and Applicants request that this rejection be withdrawn.

C. Cole *et al.* in view of Stanbury *et al.* and Puentes *et al.*

The Examiner has maintained the rejection of claims 36, 38, and 41-55, and has rejected new claim 95 under 35 U.S.C. § 103(a) as being unpatentable over Cole *et al.* (U.S. Patent No. 4,110,165) in view of Stanbury *et al.*, as applied to claims 36-38 and 41-55, and further in view of Puentes *et al.* (EP 0 182 522 A1). The Examiner has maintained the rejection of claims 36, 38, 41-55, and 95 for essentially the same reasons cited in the Final Office Action mailed January 23, 2003 and the Non-Final Office Action of February 20, 2004. The Examiner has stated that claims 36-38 and 41-55 are obvious for the reasons mentioned above. The Examiner has also stated that although neither Cole *et al.* or Stanbury *et al.* disclose clavulanic acid production from all of the microorganisms recited in claim 47, one of ordinary skill in the art would have reasonably expected that the microorganisms disclosed in Puentes *et al.* could produce clavulanic acid in the fermentation media disclosed by Cole *et al.*

The Examiner has alleged that one of ordinary skill in the art would have been motivated to substitute any of the known clavulanic acid-producing species for that disclosed in Cole *et al.* because Puentes *et al.* allegedly disclose that all of the claimed microorganisms were known at the time to produce clavulanic acid in known media containing carbon and nitrogen sources and inorganic salts. The Examiner has also alleged that the Applicants' arguments do not address the rejection under Puentes *et al.* as set forth because allegedly Puentes *et al.* is not cited for the processes disclosed therein, *per se*. Rather, Puentes *et al.* is cited for the fact that the claimed strains of microorganisms were known to be clavulanic acid producers, and one of ordinary skill in the art would have recognized Puentes' microorganisms to have been suitable in Cole *et al.*'s clavulanic acid production processes. The Examiner has alleged that such an analysis is evident from the cited prior art and does not require any hindsight reasoning. The Examiner has newly

alleged that regarding Cole *et al.*'s failure to add phosphorus during the fermentation processes, the Applicants' claims do not contain such a step.

In response, Applicants note that the rejection of claims 41, 50, and 95 has been rendered moot by Applicants' cancellation of these claims. Applicants reiterate the distinguishing arguments set forth above in response to claims 36, 38, 42-49, and 51. Applicants have amended claim 47 to include only the species *Streptomyces clavuligerus* or *Streptomyces sp. P6621*. In light of amended claims 36 and 47, Applicants submit that it would not have been obvious to one of ordinary skill in the art to substitute the *Streptomyces* species taught by Puentes *et al.* into the process taught by Cole *et al.* because amended claim 36 teaches the maintenance of the phosphorus source concentration between 0.0015% w/v and 0.15% w/v, unlike the process taught in Cole *et al.*, and amended claim 47 does not teach all of the *Streptomyces* species taught by Puentes *et al.* Even if one of ordinary skill in the art were to substitute the *Streptomyces* species of Puentes *et al.* into the process taught by Cole *et al.*, the process would not be the same as the claimed invention because the phosphorus source concentration is not maintained during the growth phase of fermentation in Coles *et al.* As mentioned above, the unexpected property of the claimed invention does not depend on what *Streptomyces* species is used, but rather, on the fact that the phosphorus source concentration is maintained during the growth phase of the fermentation after the phosphorus has been consumed, which, unlike Cole *et al.*, Stanbury *et al.*, or Puentes *et al.*, is crucial to the success of the claimed invention.

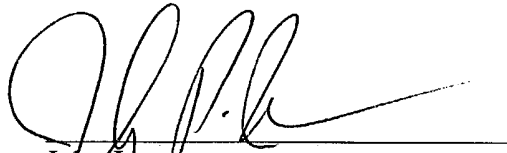
Without acquiescing in the rejection, as mentioned above, Applicants have amended claim 36 to recite the maintenance of the phosphorus concentration during the growth phase of the fermentation process. Applicants respectfully submit that the starting concentration of phosphorus and the maintenance of the phosphorus source concentration in the claim 36, as

amended, followed by the further limitations in the dependent claims of the claimed invention, are not disclosed or suggested by Cole *et al.*, either alone or in combination with, or in view of Stanbury *et al.* or Puentes *et al.* Cole *et al.* disclose various concentrations of assimilable phosphorus yielding various amounts of clavulanic acid. While Cole *et al.* teach that phosphate should be included in the fermentation medium, the examples in Cole *et al.* do not teach that the maintenance of a phosphorus source concentration is essential during the growth phase of fermentation. Nor do Cole *et al.* show any relationship between the phosphate present in the starting medium, the maintenance of a phosphate source concentration, and the yield of clavulanic acid achieved. Thus, for these reasons, Applicants submit that the claimed invention is unobvious in view of Cole *et al.*, Stanbury *et al.*, and Puentes *et al.*

IV. Conclusion

In view of the foregoing remarks and amendments, reconsideration of this application and allowance of the claims are respectfully requested. If any issues remain which the Examiner believes could be resolved through a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at 202-912-2777.

Respectfully submitted,



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December 2, 2004

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